

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING)	
PHARMACY, INC. PRODUCTS LIABILITY)	
LITIGATION)	
_____)	MDL No. 2419
)	Dkt. No 1:13-md-2419 (FDS)
THIS DOCUMENT RELATES TO:)	
)	
All Actions)	
_____)	

**SAINT THOMAS ENTITIES' RESPONSE TO PSC'S PROPOSAL FOR PLAINTIFF'S
FACT SHEET AND RECORDS AUTHORIZATIONS**

Saint Thomas West Hospital, formerly known as St. Thomas Hospital, Saint Thomas Network, and Saint Thomas Health (collectively referred to as the "Saint Thomas Entities") file this Response to the *Plaintiffs' Steering Committee's Memorandum of Law in Support of Proposals Plaintiff's Profile Form, Discovery Protocols, and Releases* (Docket #810) ("PSC Proposal Memo") in accordance with the Court's order of January 7, 2014 (Docket #748), and in support show as follows:

INTRODUCTION

The matters referred by Judge Saylor for resolution included negotiation of standardized plaintiffs' fact sheets and authorizations.¹ The Court's Scheduling Order for this hearing likewise requested the parties to meet and confer and, if necessary, submit proposals for the "precise content" of the fact sheets, releases, and protective orders.² The PSC tries to improperly interject deposition and electronically stored information ("ESI") protocols into this proceeding and has

¹ *Order on Plaintiff Fact Sheets, Authorizations to Release Records, and Protective Orders* (Dec. 23, 2013) (Docket #722) at 3-4. Although this order also references "Protective Orders," Judge Saylor has already ruled on the Saint Thomas' Entities' request to modify the protective order in this case. See Docket ##783, 784.

² *Scheduling Order* (Jan. 7, 2014) (Docket #748) ("January 7 Order") at 1-2.

gone so far as to submit its own proposals on these topics for the Court’s consideration. Judge Saylor indicated that he would begin to consider such matters at the next status conference on February 6, but in the meantime he directed “the parties to meet and confer on a discovery plan,” one involving an overview of the discovery elements in the case, such as sequencing written discovery and depositions, and an “order that directs and sets deadlines and so on”³ Although the PSC promised on several occasions to provide the first draft of such a plan, they instead circulated late last week a proposed “CMO on Trial and Bellwether Selection” and proposed that the parties file any competing bellwether and trial proposals by January 31, 2014⁴—despite the fact that Judge Saylor has made clear that the bellwether selection and initial trial process have been set aside until the discovery issues are resolved.⁵ This week, the PSC informed the Unaffiliated Defendants that it did not intend to provide any further proposals regarding discovery.⁶ Judge Saylor’s orders were carefully crafted to focus on the threshold items of discovery—fact sheets and records authorizations—and although the Saint Thomas Entities will continue to work with the PSC and other parties on the other outstanding discovery issues, they object to the PSC’s attempt to burden this hearing with discussion of other matters.

Following the Court’s instructions, the Saint Thomas Entities have set forth their compromise proposal for a Plaintiff’s Fact Sheet (“STE PFS”) and records authorizations that meet the goals of collecting adequate information to make informed decisions about bellwether trials and preserving the relevant records of the individual MDL Plaintiffs. As explained in the *Saint*

³ See Transcript of Jan. 10, 2014, Status Conference (Exhibit A) at 48-50.

⁴ See Declaration of Yvonne K. Puig of Jan. 31, 2014 (“Puig Decl.”) (Exhibit B) at ¶ 2 & Exhibit B-1.

⁵ See *Order on Timetable for Determining “Bellwether” Cases* (Dec. 23, 2013) (Docket #721).

⁶ *Id.* at ¶ 3 & Exhibit B-2.

Thomas Entities' Memorandum of Law in Support of Proposal for Plaintiffs' Fact Sheet and Records Authorization,⁷ the Saint Thomas Entities' proposal included a number of concessions from the original Fact Sheet they proposed at the December 13, 2013, status conference before Judge Saylor. The PSC criticizes the effort, complaining that the STE PFS still seeks too much information and goes so far as to suggest that these defendants are “now requesting more information than in the profile form they previously submitted to this Court.”⁸ Hyperbole notwithstanding, the only such additional information the PSC can identify are the additional blanks for the Plaintiffs to answer whether they have had “cirrhosis, hepatitis, kidney failure, and depression”⁹—blanks that members of the PSC asked these defendants to add in order to provide more precise information than what was in the prior version.¹⁰

The PSC's suggestion that it has done all the compromising is spurious, considering the point where it started. As Judge Saylor indicated in referring these matters to this Court, “the proposed form suggested by the PSC would not provide sufficient information to make a meaningful analysis of a case for purposes of selecting potential ‘bellwether’ cases.”¹¹ Instead, he found that “[t]he defendants will need *substantial additional information* in order to understand the history and circumstances of a particular plaintiff and his or her claim in order to evaluate whether it is a typical or representative case that could be used as a bellwether case.”¹² And, as

⁷ Docket #808 (“STE Proposal Memorandum”).

⁸ PSC Proposal Memo at 1.

⁹ *Id.* at 7.

¹⁰ See Docket #592-4 at 14 (requesting a “Yes,” “No,” or “Don’t Recall” answer to whether the Plaintiff had had “Liver disease or jaundice” or “Depression or emotional issues requiring medication”).

¹¹ Order of December 23, 2013 (Docket #722) (“Fact Sheet Referral Order”) at 2.

¹² *Id.* (emphasis added).

the redlined draft attached to the STE Proposal Memo demonstrates,¹³ the Saint Thomas Entities have also moved toward the middle and made substantive changes in a spirit of compromise. The fact that the PSC started at such an extreme position does not make the Saint Thomas Entities' position unreasonable. The Saint Thomas Entities reurge their request that the Court adopt their proposed STE PFS and authorizations.

BACKGROUND

The PSC sets out a self-serving version of the history of the negotiations in an attempt to resolve these matters before the hearing set for February 6, 2014. In accordance with Judge Saylor's direction and this Court's January 7 Order, the parties have spent considerable time meeting and conferring and exchanging drafts of proposed fact sheets/profile forms, and both sides have made concessions in an effort to try and reach a compromise. Contrary to the PSC's assertions, this has not been a one-sided process with the PSC doing all the work and the Unaffiliated Defendants being dilatory. The Declaration of Marcy Hogan Greer, filed prior to the December 13, 2013, status conference demonstrates that the Saint Thomas Entities have been quite diligent in moving forward with this process.¹⁴ But there are still some issues where the parties' positions cannot be reconciled, necessitating this Court's intervention, as explained below.

ARGUMENT AND AUTHORITIES

The PSC's entire argument is focused on its ill-supported claim that the Saint Thomas Entities have not made enough concessions to shorten the Fact Sheet. They repeatedly charge that the STE PFS is "unnecessarily detailed" and seeks information of "marginal materiality or relevance." *E.g.*, PSC Proposal Memo at 9. They count the additional pages and items they have

¹³ See STE Proposal Memo at Exhibit M (Docket #808-13).

¹⁴ See Declaration of Marcy Hogan Greer (Docket #593), attached for the Court's reference as Exhibit C.

added and make comparisons of the volume of changes made by each party. *Id.* at 5, 7. That is not the point. It is the nature of the information requested that should be the Court’s focus. The Saint Thomas Entities and defendant Saint Thomas Outpatient Neurosurgical Center (“STOPNC”) have collectively provided the Court with actual fact sheets/profile forms approved by courts in *nine* different MDLs (or state-coordinated, mass tort proceedings), many of which were provided to Judge Saylor at the December Status Conference. These forms require the same—or often more—information than the STE PFS. Although the PSC was aware of a number of these cases from prior status conferences and meet-and-confers, the PSC does not mention *any* of these cases. Instead, the PSC points to a profile sheet from a single MDL that is along the same lines of the “Confidential Personal Injury or Wrongful Death Claim Information Form” from the Bankruptcy Court that Judge Saylor has already determined does not, for this case, “provide sufficient information to make a meaningful analysis of a case for purposes of selecting potential ‘bellwether’ cases.” Fact Sheet Referral Order at 2. The Saint Thomas Entities will address the PSC’s individual concerns below.

A. The Family Medical History Is Highly Relevant at This Point

The fact/profile sheets presented to the Court as examples of forms adopted and used by other courts universally seek family history information. Yet the PSC claims that it would be burdensome and invasive for the individual Plaintiffs to have to answer similar questions here. *E.g.*, PSC Proposal Memo at 7-8. In support of their argument, they cite to cases that are entirely inapposite. *S.C. Med. Ass’n v. Thompson*, 327 F.3d 346 (4th Cir. 2003), simply recognizes the laudatory purposes of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), and the other cases cited by the PSC involve requests by defendants to seek *the medical records* and, in some cases, independent medical examinations, of family members who are not parties to the lawsuits. *See, e.g., Kunz v. S. Suburban Hosp.*, 761 N.E.2d 1243, 1248-49 (Ill. App. 2001)

(finding that medical records of non-party siblings were not subject to production); *In the Matter of New York County DES Litig.*, 168 A.D.2d 44, 45-46, 570 N.Y.S.2d 804 (N.Y. App. 1991) (denying defendants' attempt to obtain medical records of DES plaintiffs' mothers, fathers, siblings, and other family members); *Dierickx v. Cottage Hosp. Corp.*, 393 N.W.2d 564, 565-66 (Mich. App. 1986) (defendant hospital sought to compel medical records and medical exams of minor, non-party siblings of the malpractice plaintiff to show that the plaintiff likely had a genetic disorder not attributable to any action or omission by the hospital). Of course, the Saint Thomas Entities are not seeking medical records of Plaintiffs' family members at this point. They only propose asking the Plaintiffs—who have put their own health in issue—to answer a few yes or no questions as to whether they have a family history of certain diseases and disorders that may impact their experiences and outcomes related to the claims they make in this litigation. This information is highly relevant. As the Saint Thomas Entities have previously noted, there are significant differences in the acuity of these patients in that many received the NECC steroids, but comparatively few had significant adverse health effects. Hereditary conditions that may demonstrate susceptibility could be very important to understanding individual claims. In fact, as the trial court aptly noted in the *DES* opinion, “[t]he taking of a detailed family history by a physician is generally a routine part of the treatment process. . . .” *DES*, 168 A.D.2d at 46. Doctors, like other MDL courts, have recognized the importance of understanding the familial history when it comes to assessing a patient's health.

B. Plaintiffs' History of Use of Tobacco, Alcohol, and Other Known Confounding Substances Is Vital to Understanding Their Health Presentation

The PSC wants to limit inquiry into individual use of tobacco, alcohol, and illicit drug use by predicated their need to provide specific information about such use on a threshold question of whether they are currently doing so. Although the PSC makes a half-hearted attempt to claim

that this information is not relevant, PSC Proposal Memo at 8, that is certainly not the case. The STE PFS proposes simply asking questions about prior and current use that are virtually standard in the fact/profile sheets used in other MDLs. There can be no serious suggestion that tobacco and drug use, and heavy use of alcohol, have no adverse health effects. The Court only need to look at the label on a bottle of Tylenol or Motrin to see warnings about heavy consumption of alcohol mixed with these over-the-counter products. And the burden to the Plaintiffs is minimal—if a particular Plaintiff is a “teetotaler” (the term used by the PSC), then he or she only need check the right box on the form.

C. The Plaintiffs’ Medical Histories Should Extend Back Ten Years

As the Saint Thomas Entities predicted, the parties disagree as to whether the individual Plaintiffs’ relevant medical history period should be ten years or limited to five (or seven) years. The PSC’s protestations about how it “cannot conceivably see” how a longer medical history is relevant are lawyer diatribe, entirely unsupported by any authority, much less medical basis. As the exemplar fact/profile sheets demonstrate, ten years of history is standard, and some go back even farther in time. At least ten years of medical history is necessary to assess health trends and insure that previously observed conditions that have long been present in a particular plaintiff are covered by a sufficient array of the medical records.

D. Plaintiffs’ Attempt to Limit Social Security and Workers’ Compensation Records to “Awards” Is Not Warranted

Plaintiffs have again raised relevance challenges to the questions asking about prior applications for Social Security disability and workers’ compensation benefits. They have insisted that only applications that resulted in actual awards be disclosed. Defendants have made a number of concessions in terms of scope in an effort to come to a compromise on this question, but the PSC has refused to compromise. How a plaintiff has characterized a claimed disability to

regulators to obtain benefits can be very important; there are often instances of inconsistent positions taken before the regulators and in personal injury suits regarding the same claim. *See, e.g., Cleveland v. Policy Mgmt. Sys. Corp.*, 526 U.S. 795, 806-07 (1999) (collecting cases in which parties had taken positions in proceedings to recover benefits under the Social Security Disability Insurance program that were factually inconsistent with their claims in civil lawsuits asserting unlawful discrimination). The Saint Thomas Entities’ proposals to limit these questions both in time and scope to cover applications for disabilities lasting more than 60 days and going back ten years are eminently reasonable and should be adopted.

E. The Document Requests Are Limited, But Very Important to This Stage of the Litigation

It is not clear why the PSC suggests that the Saint Thomas Entities have not made compromises on their document requests. PSC Proposal Memo at 7. In fact, the Saint Thomas Entities originally made 21 requests, and the current proposal is for 9—two of which the PSC agrees should be included. Other than to complain about the number, the PSC challenges only one document request in particular¹⁵—Request No. 9 (formerly Request No. 21). That request seeks: “All documents in your possession, or in the possession of your attorneys, that you or your attorneys obtained directly or indirectly from the Defendants, *other than documents produced by the Defendants in this litigation.*” STE PFS Docket #808-1 at 17 (emphasis added). The request is clearly directed at documents that the Plaintiffs have obtained outside the course of discovery,

¹⁵ The PSC complains about “Request No. 6,” which they claim relates to disability and workers’ compensation claims, *see* PSC Proposal Memo at 8, but they must be viewing a different draft. The current STE PFS proposes instead that the Saint Thomas Entities obtain the records through releases, not that the Plaintiffs have to produce any such documents at this juncture. *See* Docket #808-1 at 17. “Request No. 19” has also been eliminated. *Id.*

and so the suggestion that it implicates “hundreds of thousands of pages of documents,” PSC Proposal Memo at 9, is makeweight.

F. The Records Authorizations Proposed by the Saint Thomas Entities Should Be Adopted

It is ironic that the PSC suggests that it has carried the water on the authorizations from the outset. In fact, the Saint Thomas Entities were the ones who prepared and circulated the first drafts in November 4, 2013, and other than one proposal as to the medical authorizations (which attempted to carve out a number of medical conditions and require submission of all records to a central repository controlled by the PSC), the PSC did not submit its own written proposals. In fact, the PSC circulated its first written proposals for authorizations (other than the single one for medical records) last Friday, January 24, 2014, an hour before the filing deadline. *See* Puig Declaration at ¶ 2 & Exhibit B-1.

As noted above, the Deposition and ESI protocols are not currently before the Court, and the parties’ dispute about Social Security disability and workers’ compensation records mirror the discussion at Part D above. The employment and tax record releases have been agreed. The PSC does not mention the educational records release proposed by the Saint Thomas Entities—much less do they explain why those records are not necessary. As to the medical records release form, the ten-year scope should be adopted for the reasons set forth in Part C above. The PSC makes no argument about why it should be able to carve out psychological, sexual abuse and drug/alcohol addiction records because it has no defensible position. It would be highly inappropriate to deny this discovery as to any Plaintiff who seeks emotional harm or damages of any kind.

Finally, the PSC’s proposal that all medical records be funneled through their own proprietary repository should be rejected. The defendants should be in a position to obtain the records directly from the third-party providers without being charged an access fee by the PSC and

without the risk that the PSC will attempt to unilaterally control what documents are actually produced. Again, they cite no authority for their unorthodox proposition, and so should not be allowed to hijack the discovery process in this way.

CONCLUSION AND PRAYER

For these reasons and those set forth in the STE Proposal Memo, the Saint Thomas West Hospital, formerly known as St. Thomas Hospital, Saint Thomas Network, and Saint Thomas Health respectfully request that the Court: (i) approve and adopt their proposed Plaintiff's Fact Sheet (Exhibit A to STE Proposal Memo) and order that each Plaintiff in the MDL with claims against the Saint Thomas Entities complete the approved form within 60 days of the date of its order; (ii) approve and adopt their proposed records authorizations (Exhibits B-E to STE Proposal Memo) and order execution of such authorizations by all Plaintiffs with claims against these Defendants within 60 days of the date of the order; and (iii) grant such other and further relief to which the Saint Thomas Entities are entitled.

Respectfully submitted,
SAINT THOMAS WEST HOSPITAL,
FORMERLY KNOWN AS ST. THOMAS
HOSPITAL, SAINT THOMAS NETWORK,
AND SAINT THOMAS HEALTH

By its attorneys,
/s/ Sarah P. Kelly
Sarah P. Kelly (BBO #664267)
skelly@nutter.com
NUTTER McCLENNEN & FISH LLP
Seaport West
155 Seaport Boulevard
Boston, Massachusetts 02210
(617) 439-2000
skelly@nutter.com

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OF COUNSEL:

Yvonne K. Puig*
Texas State Bar No. 16385400
Eric J. Hoffman*
Texas State Bar No. 24074427

FULBRIGHT & JAWORSKI L.L.P.
98 San Jacinto Blvd. Suite 1100
Austin, Texas 78701
(512) 536-2450
(512) 536-4598 (FAX)

*Appearing *Pro Hac Vice*

CERTIFICATE OF SERVICE

This certifies that a true and accurate copy of the foregoing was served on all parties of record by virtue of the Court's electronic filing system this 31st day of January, 2014.

/s/ Sarah Kelly

SARAH KELLY